REMARKS/ARGUMENTS

The Present Invention

Background

The present invention relates to an electrocardiograph (ECG) grounding circuit for use in carrying out both 5-lead ECG signal acquisition and 12-lead signal acquisition. When operating in the 5-lead mode, the circuit is able to limit amount of the current to which the patient is exposed should additional conductors be connected to the patient. The circuit is also able to detect when such additional conductors are connected to the patient so that the operation of electrocardiograph may be altered accordingly.

Electrocardiography is a fundamental medical diagnostic tool that allows a clinician to view the electrical activity of the heart thereby providing valuable medical information about the patient. An electrocardiogram is typically collected in one of two basic configurations: a 5-lead ECG which comprises electrodes placed at the limbs of the patient, and the 12-lead ECG which uses the leads of the 5-lead ECG in combination with a plurality of precordial electrodes placed around the chest of the patient. (Spec page 1, lines 18-23, Figs. 1, 3) Each configuration has both advantages and limitations that a clinician must weigh before deciding upon a configuration to use.

A 5-lead ECG provides basic cardiac information that is often sufficient for the purposes of the clinician. The circuitry and ECG collection systems for 5-lead ECG are simple and economical. This translates into greater availability of 5-lead ECG monitors in clinical settings and provides a cost-effective solution for the collection of ECG signals.

A 12-lead ECG, however, provides more in-depth cardiac information that allows the clinician to perform more complex analysis of the patient's medical condition. But a 12-lead ECG system is more costly, and as a result, there are fewer devices available in a typical hospital. Further, the additional leads of the 12-lead ECG are more susceptible to interference from other electronic medical equipment that may be in use on the patient. The 12-lead ECG also adds additional connections to the patient who may be already crowded with other medical treatment and diagnostic connections.

Therefore, it is desirable to have an ECG system that is able to collect signals from either a 5-lead ECG configuration or a 12-lead ECG configuration from the same data collection port. This creates a robust ECG system that provides cost efficiencies because two ECG devices may be combined into a single ECG device and diagnostic efficiencies as it provides the clinician with the ability to use the most desirable ECG configuration for the patient at any given time.

Circuitry of the Present Invention

In an embodiment of the present invention shown in Figs. 3 and 4, an ECG cable (12) is connected to a signal acquisition collection connector (13) of an ECG device, such as an electrocardiograph or ECG monitor (30). Five ECG signal conductors are needed for 5-lead ECG. Ten ECG signal conductors are needed for 12-lead ECG. The collection connector comprises a plurality of connections (14) that are in a configuration that is able to receive the ten conductors for acquiring both 12-lead ECG signal data and 5-lead ECG signal data. See page 7, lines 14-28 and upper, right side schematic shown in Fig. 4. The connector will also receive five conductors if only 5-lead ECG signal acquisition is desired, as shown in the lower right side schematic of Fig. 4.

The plurality of connections (14) in the connector (13) comprise a first set of connections that link a first set of 5-lead ECG conductors to ECG device preamplifiers (35), shown in the upper portion of Fig. 4. The plurality of connections (14) also comprises a second set of connections that connects a second set of additional 12-lead ECG conductors to the second preamplifiers (35), shown in the lower portion of Fig. 4 of the ECG device, that allow 12-lead ECG signal acquisition to be carried out (Spec page 7, line 30 to page 8, line 6).

A switch (18,19,20,21,22) is also connected to each of the leads of the second set of conductors that, in a closed position, connects the conductors of the second set to a grounding circuit (28,29,31,G) and a signal detection circuit (32). Briefly, and as hereinafter described in detail, when the switches are in a closed position, the grounding circuit establishes the potential of the second, 12-lead set of conductors at a virtual or "floating" ground, preventing any signal in the second set of conductors from being sent to the preamplifiers (35) thus allowing 5-lead ECG signal acquisition to be carried out (Spec page 8, lines 6-11). The signal detecting circuit

monitors the second set of leads when the switches are in a closed position to determine if any of the signal set of 12-lead ECG conductors leads are connected to a patient and provides an output indicative of such connection.

Operation of the Circuitry of the Present Invention

The operation of the present invention in the depicted embodiment is as follows.

Operation in the 5-lead mode - If the clinician wished to acquire 5-lead ECG signal data with 12-lead conductors connected to collection connection (13), he/she connects only the 5-lead ECG conductors to the patient for ECG monitoring. The switches (18, 19, 20, 21, 22) for the remaining 12-lead conductors are in the open position. The device would then confirm that no conductors of the second set of 12-lead conductors are connected to the patient by examining the outputs of the preamplifiers (35) in the lower portion of Fig. 4. In the absence of such connections, no ECG signal will be detected in the conductors of the second set and the switches will then be closed, connecting the second set of conductors to the grounding circuit (28, 29, 31 G). The connection of the second set of conductors to the grounding circuit results in the effectual grounding of the unused 12-lead ECG conductors, preventing unwanted signals from being applied to the ECG device.

The acquisition of 5-lead ECG signal data is then carried out.

Connection of additional conductors - If one or more of the second set, 12-lead ECG conductors are inadvertently or intentionally connected to the patient while the ECG device is monitoring only the signals from the first set, 5-lead ECG conductors, the following can occur. The right leg driver (34) conductor of the first set of conductors injects a signal into the patient at the patient's right leg. (Spec page 2, lines 17-29) This signal is used in the ECG signal acquisition to improve the common mode rejection ratio of the acquired ECG signals. In systems depicted in the prior art, such as U.S. Patent No. 6,553,250 to Rantala, when the second set of conductors are connected directly to actual ground, as opposed to grounding through the grounding circuit of the present invention, then the connection of a conductor of the second set to the actual ground produces a low impedance pathway from the right leg driver conductor through the patient to the actual ground, thus placing the patient at risk from high current in the

low impedance pathway and pushing the right leg driver circuitry (not pictured) out of its operational mode into saturation. (Spec page 4, lines 1-21)

To avoid the foregoing, the grounding circuit in this embodiment of the present invention produces a current limiting function that causes the current flowing through such a pathway to remain both in the operational range of the right leg drive circuitry and within acceptable safety ranges for the patient. (Page 5, lines 3-34) The current limiting feature of the grounding circuit may be accomplished with the use of an operational amplifier (28) in a configuration that increases the output impedance of the operational amplifier as the current received from the low impedance pathway increases. The increased output impedance serves to limit the current in the low impedance pathway to a level that is safe for the patient and maintains operation of the right leg drive circuit. (Page 8, line 28 through page 9, line 2)

The grounding circuit of this embodiment of the present invention also has the following feature. As noted in the newly cited U.S. Patent to Simon et al., U.S. Patent 4,577,639, most modern electrocardiographs have means for determining the status of the electrode connection to a patient and operating the ECG device accordingly. Thus, the present invention, in addition to the patient safety, current limiting feature, also provides a means for indicating when additional electrodes have been connected to the patient. (Spec page 5, line 35 through page 6, line 15) This is carried out in the following manner.

With the switches in the closed position, the second set of conductors are also connected to a signal detection circuit connected to the operational amplifier. The signal detection circuit may comprise a voltage comparator (32) biased to a reference voltage. The increase in the current limiting impedance of the operational amplifier resulting from the connection of one or more of the 12-lead ECG conductors to the patient will cause the voltage input to the comparator to exceed the reference voltage for the signal detecting circuitry and cause the signal detecting circuit to provide an output indicating that one or more of the 12-lead ECG conductors have been connected to the patient. (Spec page 9, line 25 through page 10, line 2) The output can be used to cause an opening of the switches so that the signal(s) in the connected conductor(s) will be provided to the respective preamplifier(s) and to the ECG device. (Page 9, line 35 through page 10, line 2)

Operation in the 12-lead mode - If the clinician wished to acquire 12-lead ECG signal data, he/she connects the first set, 5-lead ECG conductors to the patient and the second set, 12-lead ECG conductors to the patient. The switches for the 12-lead conductors are in the open position. The device then confirms that the conductors of the second set of conductors are connected to the patient by examining the outputs of the preamplifiers (35) in the lower portion of Fig. 3. In the presence of such connections, ECG signals will be detected in the conductors of the second set and the switches will remain open, connecting the second set of conductors to the preamplifiers (35) and the ECG device for 12-lead ECG signal acquisition.

Alternative 5-lead operation - If the clinician knows that the patient only requires 5-lead ECG analysis, the clinician attaches a 5-lead ECG conductor set to the collection connector (13). These conductors can have wire shields protecting each of the conductors from interference due to other electrical equipment in the vicinity. To be effectual, the shields must be connected to a ground. Therefore, the electrode signal conductors are connected to the first set of connections (14_1) in the collection connector and the wire shields are connected to the second set of connections (14_2). (Page 8, lines 6-11, Fig. 2) The ECG device operates in the same fashion as previously described. However, there will be no signals collected by the shields and thus transmitted to the preamplifiers (35) in the lower portion of Fig. 3. In the absence of a signal, the switches go to the closed position and the wire shields are held at the desired grounded potential through the grounding circuit. (Page 8, lines 6-11)

This feature produces an economical advantage in that medical care facilities can get the functionality of both a 12-lead ECG device and a 5-lead ECG device from a single ECG acquisition device.

The Applied Simon et al. Reference

The Simon et al. '639 reference newly cited in the Office Action of February 14, 2006 shows an apparatus and method for determining the condition of electrodes attached to a patient and selecting a lead configuration employing those electrodes having satisfactory connections. The quality of the connection is determined by the impedance found in the electrode. For this purpose a small current is passed through each active electrode and the resulting voltage ascertained. If the voltage exceeds a threshold, indicating that the impedance

is high and the connection to the patient poor, a CPU alters the ECG lead configuration accordingly to employ those electrodes that have a satisfactory connection.

Argument for Allowance

The claims now pending in this application are directed to a grounding circuit for ensuring that a patient is not subjected to currents in excess of regulatory standards should a 12-lead ECG signal acquisition conductor be connected to the patient when 5-lead ECG signal acquisition is being carried out. To this end, the circuitry employs a grounding circuit interposed between the conductors of a second set of 12-lead conductors and a relative or virtual ground. This grounds the additional connector(s) of the second set when they are not being used to avoid degradation of the ECG signal acquired by the 5-lead conductors of a first set of conductors. A low impedance signal path is presented to ensure proper grounding of the additional conductor(s).

Should one or more signal conductors of the second set be connected to the patient, current will appear in the conductor from the right leg drive electrode of the 5-lead, first conductor set and the low impedance path to ground presents the potential for current in excess of patient safety regulatory requirements and in excess of the operating range of the right leg drive circuitry. To avoid this, the grounding circuit of the present invention thus includes means creating a high impedance path upon the appearance of current in a conductor of the second set should the conductor be connected to the patient, thereby to limit the current to which the patient is exposed and maintain operation of the right leg drive circuitry.

The Simon et al. '639 patent contains no teaching of any such current responsive, differing impedance grounding circuit means. This is clearly shown in Fig. 3 of the patent. It is quite clear from that figure that there is no element, let alone a two impedance state path circuit means interposed between the switches 232-236 and ground.

Inasmuch as the Simon et al. reference is totally devoid of any teaching or suggestion of the grounding circuit now recited in the amended claims, the claims are deemed patentable over this reference.

Claims 21-23 relating to the sensing means for determining that an electrode of the second set has been connected to a patient depend from main independent claim 19 the

allowability of which is urged, above. Further, they describe the sensing means as responsive to the operating condition of the grounding circuit means that is interposed between the switch and ground. As noted above, no grounding circuit means interposed between a switch means and a ground connection is taught or suggested by the Simon et al. reference. These claims are similarly deemed to be allowable. The same is also true of claims 20 and 24 directed to further features of the inventive grounding circuit.

Withdrawal of the rejection made in the Office Action of February 14, 2006 and passage of this application to allowance is respectfully requested.

Respectfully submitted,

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